USDA Quality System Assessment (QSA) Program

1 Purpose

This Procedure provides the requirements of a USDA Quality System Assessment (QSA) Program. It also provides the criteria used in the objective evaluation of USDA QSA Programs that are submitted for approval. Evaluations are conducted by the Agricultural Marketing Service (AMS), Livestock and Seed (LS) Program, Audit, Review, and Compliance (ARC) Branch

2 Scope

This Procedure applies to marketing programs for agricultural products, including services, that are submitted to the ARC Branch for verification and monitoring. It is limited to programs or portions of programs where specified product requirements are supported by a documented quality management system. The extent of controls included in these programs may include all phases of production and marketing from genetic development through retail distribution, or any portion as described in the scope of the submitted program.

If any program requirements can not be applied due to the nature of a company and its product, then these requirements may be considered for exclusion. Exclusions are limited to program requirements within *Clause 4 Product Realization* and must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

3 References

ARC 1000 Procedure, Quality Systems Verification Programs General Policies and Procedures
Applicable ARC Branch Program Procedure

4 Responsibilities

Companies must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

The ARC Branch must meet all applicable policies and procedures outlined in this Procedure, the applicable Program Procedure, and *ARC 1000 Procedure, Quality Systems Verification Program General Policies and Procedure*.

5 Audit Frequency

All approved programs will be audited at least twice per fiscal year (October 1 to September 30). However, more frequent audits may be conducted (1) if either numerous major or minor non-conformances are identified during an audit; (2) if customer complaints indicate an ongoing problem; (3) to satisfy specific requests as declared by customers, trading partners or other financial interested parties; or (4) as directed by the ARC Branch Chief.

6 Listing of Approved Programs

Approved programs will be listed on the applicable Program website or on the USDA QSA Program website at http://www.ams.usda.gov/lsg/arc/qsap.htm. Information about the approved program will be in accordance with the applicable Program Procedure. The approved program listing on the USDA QSA Program website will include the following information:

a) Company name;
b) Company contact information;
c) Program requirements;
d) Report reference number (approval number); and
e) Renewal date.

7 Program Requirements (Clauses 1 to 5)

Companies must submit a documented program that addresses the program requirements as outlined in the following clauses (Clauses 1 to 5).

1 Quality Management System

1.1 General Requirements

A quality management system (QMS) must be established, documented, implemented, and maintained which ensures that products conform to the requirements of this Procedure, the applicable Program Procedure, and to specified product requirements.

1.2 Documentation Requirements

1.2.1 General

The company must prepare and maintain a QMS that includes:

a) Documented specified product requirements;
b) A quality manual;
c) Documented procedures required by this Procedure;
d) Documents necessary to ensure the effective operation and control of its processes; and
e) Records required by this Procedure.

1.2.2 Quality Manual

The company must establish and maintain a quality manual that includes at a minimum:

a) An organizational chart or similar document listing all personnel assigned to managerial positions within the program;
b) A description of the scope of the QMS, including details of and justification for exclusions;
c) The specified product requirements;
d) Documented procedures established for the QMS;
e) A master document list that shows the most current issue of all QMS procedures, forms, tags, and labels used to track or demonstrate conformance; and
f) All other documentation as required by this Procedure.

The quality manual must be controlled and available for review at all associated sites where activities are conducted.

1.2.3 Control of Documents

The company must control all documents required by this Procedure.

Control of documents includes at a minimum:

a) All documents must contain the current revision status of the document.
b) The company must ensure that relevant versions of applicable documents are available at all associated sites where activities are conducted.
c) The company must prevent the use of obsolete or unapproved documents.
d) All documents must be retained for a minimum of 1 year.

Substantive changes to QMS documentation must be submitted to the ARC Branch for approval prior to implementation.

1.2.4 Control of Records

The company must establish and maintain records to provide evidence of conformity to program requirements, to specified product requirements, and of the effective operation of the QMS.

Control of records includes at a minimum:

a) The company must control all records required by this Procedure.
b) Records must be stored in a manner so as to prevent loss, damage, or alteration.
c) Records must be legible, easily accessible, and readily available.
d) All records must be retained for a minimum of 1 year.

2 Management Responsibility

Management must ensure that specified product requirements are established at relevant functions and levels within the company.

Management must ensure that QMS responsibilities and authorities are defined and communicated within the company.

The company must have an organizational chart or similar document listing all personnel assigned to managerial positions within the program.

All personnel listed must have their responsibilities and authorities outlined in an auditable method.

A management representative, who has the authority to act on behalf of the company at all locations where program activities are conducted, must be designated.

The management representative must have the responsibility and authority for ensuring that processes needed for the QMS are established, implemented, and maintained.

3 Human Resources - Competence, Awareness, and Training

Personnel performing work affecting product quality must be competent on the basis of appropriate education, training, skills, and/or experience, as applicable.

The company must provide training to all personnel with QMS responsibilities.

The company must have a documented procedure to ensure all personnel performing work affecting product quality are properly trained in relevant aspects of the QMS.

The documented procedure must define the methods for:

a) Determining the necessary competence for personnel performing work affecting product quality;
b) Determining the criteria for training;
c) Evaluating the effectiveness of the training; and
d) Ensuring that personnel are aware of the relevance and importance of their activities and how they contribute to the achievement of the quality objectives.

The company must maintain appropriate records of education, training, skills, and experience, as applicable. These records must include the scope of the training received.

4 Product Realization

4.1 General

Where any program requirements within *Clause 4 Product Realization* can not be applied due to the nature of a company and its product, these requirements may be considered for exclusion. Exclusions must not affect the company's ability to provide a conforming product. Additionally, exclusions do not affect the company's responsibility to provide a conforming product.

4.2 Receiving Process

The company must ensure that product purchased or received from outside establishments and used in the program conform to specified receiving requirements.

The company must ensure the adequacy of specified receiving requirements prior to their communication to the supplier.

The company must evaluate and select suppliers based on their ability to supply product that conforms to the specified receiving requirements.

The company must establish and implement the inspection or other activities necessary for ensuring that product purchased or received from outside establishments and used in the program conform to specific receiving requirements.

The company must have a documented procedure addressing products purchased or received from outside establishments.

The documented procedure must describe:

a) All product purchased and/or received from outside establishments regardless of its use within the program;
b) The specified receiving requirements for acceptance of products to be used in the program;
c) The criteria and process for supplier selection, evaluation, and re-evaluation; and
d) The process used to ensure that purchased product and/or product received from outside establishments and used in the program conform to specific receiving requirements.

The company must maintain records of the results of supplier evaluations and any necessary actions arising from the evaluation.

The company must maintain records to provide evidence of conformity to the receiving process and of the effective operation of the receiving process.

4.3 Identification and Traceability

The company must have a documented procedure to identify product (raw materials and/or finished product) by suitable means throughout product realization, where appropriate.

The documented procedure must describe the method for:

a) Identifying the product throughout product realization;
b) Controlling and recording the unique identification of the product; and
c) Identifying the product status with respect to monitoring and measurement requirements.

The method for identifying the product must:

a) Be unique to the program. When applicable, animals must be identified with ear tags or other permanent identification; and
b) Be such that the identification will transfer through all phases of product realization, from receipt into the program through production to delivery.

The company must maintain records of all products as identified and records of all changes of identities.

4.4 Preservation of Product

The company must preserve the conformity of product during internal processing and delivery to the intended destination.

The preservation must include identification, handling, packaging, storage, and protection. It must also apply to the constituent parts of a product.

4.5 Control of Monitoring and Measuring Devices

The company must determine the monitoring and measurement to be undertaken to provide evidence of conformity to specified product requirements.

The company must determine the monitoring and measurement devices needed to provide evidence of conformity to specified product requirements.

The company must establish processes to ensure that monitoring and measurement can be conducted and are conducted in a manner that is consistent with the monitoring and measurement requirements.

Where necessary to ensure valid results, measuring equipment must:

a) Be calibrated or verified at specified intervals, or prior to use, against measurement standards traceable to international or national measurement standards; where no such standards exist, the basis used for calibration or verification must be recorded;
b) Be adjusted or re-adjusted as necessary;
c) Be identified to enable the calibration status to be determined;
d) Be safeguarded from adjustment that would invalidate the measurement result; and
e) Be protected from damage and deterioration during handling, maintenance, and storage.

The company must assess and record the validity of the previous measuring results when the equipment is found not to conform to the requirements. The company must take appropriate action on the equipment and any product affected.

The company must confirm the ability of computer software to satisfy the intended application when used in the monitoring and measurement of specified requirements. This must be performed prior to initial use and reconfirmed as necessary.

The company must maintain records of the results of calibration and verification.

5 Measurement, Analysis, and Improvement

5.1 General

The company must plan and implement the monitoring, measurement, analysis, and improvement processes needed:

a) To demonstrate conformity of the product;
b) To ensure conformity of the QMS; and
c) To continually improve the effectiveness of the QMS.

The plan must include a determination of application methods, including statistical techniques, and the extent of their use.

When statistical methods are used to control product quality or integrity, the basis for those procedures must be clearly defined.

5.2 Monitoring and Measurement

5.2.1 Customer Satisfaction

The company must monitor information relating to customer perception as to whether the company has met customer requirements. This information must be reviewed as a performance measurement of the QMS.

The company must determine the methods for obtaining and using this information.

The company must maintain records relating to customer perception.

5.2.3 Monitoring and Measurement of Processes

The company must apply suitable methods for monitoring and, where applicable, measurement of the QMS processes.

These methods must demonstrate the ability of the processes to meet product requirements.

When product requirements are not achieved, correction and corrective action must be taken, as appropriate, to ensure conformity of the product.

5.2.4 Monitoring and Measurement of Product

The company must monitor and measure the characteristics of the product to verify that product requirements have been met. This must be conducted at appropriate stages of the product realization process.

The company must ensure that product requirements have been meet prior to product release and service delivery, unless otherwise approved by a relevant authority and, where applicable, by the customer.

The company must maintain records to verify evidence of conformity to product requirements. Records must indicate the person(s) authorizing release of product.

5.3 Control of Non-conforming Product within the QMS

The company must ensure that non-conforming product (raw material and/or finished product) is identified and controlled to prevent its unintended use or delivery.

The company must have a documented procedure that defines:

a) The identification of non-conforming product;
b) The controls used to ensure the segregation of non-conforming product; and
c) The related responsibilities and authorities for ensuring the segregation and disposition of non-conforming product.

The company must handle non-conforming product by one or more of the following methods:

a) By taking action to eliminate the detected non-conformity;
b) By authorizing its use, release, or acceptance under concession by a relevant authority and, where applicable, by the customer; or
c) By taking action to preclude its original intended use or application.

When non-conforming product is corrected, it must be subject to re-verification to demonstrate conformity to the product requirements.

The company must take appropriate actions when non-conforming product is detected after delivery or use has started.

The company must maintain records of all non-conforming product and any subsequent actions taken, including concessions obtained.

5.4 Improvement

5.4.1 Continual Improvement

The company must continually improve the effectiveness of the QMS through the use of the quality objectives, customer feedback, audit results, and corrective and preventative actions.

The company must ensure that the integrity of the QMS is maintained when changes to it are planned and implemented.

5.4.2 Corrective Action

The company must take action to eliminate the cause of non-conformance in order to prevent recurrence.

Corrective actions must be appropriate to the effects of the non-conformances encountered.

The company must maintain records of the results of any actions taken.

5.4.3 Preventative Action

The company must determine and implement action to eliminate the causes of potential non-conformances in order to prevent their occurrence.

Preventative actions must be appropriate to the effects of the potential problems.

The company must maintain records of the results of any actions taken.

Appendix A - Definitions

Conforming Product – product within the QMS that meets, and can be verified as meeting, the specified product requirements. Such product must be identified as meeting the specified product requirements in accordance with the QMS and the applicable Program Procedure.

Corrective Action – action to eliminate the cause of a detected non-conformance.

Correction – action to eliminate a detected non-conformance.

Customer Satisfaction – customer's perception of the degree to which the customer's requirements have been fulfilled.

Non-conforming Product – product within the QMS that does not meet, or can not be verified as meeting, the specified product requirements. This includes raw materials and finished products. Non-conforming raw materials must be excluded from use within the program; and non-conforming finished products must be excluded from delivery.

Preventative Action – action to eliminate the cause of a potential non-conformance.

Process – a set of interrelated or interacting activities which transforms inputs into outputs.

Product – a raw material or a finished good. The type of product depends upon where it is within product realization.

Product Realization – the process of developing a product from initial acceptance of the raw materials through production to delivery.

Product Requirements – includes, but is not limited to, the requirements of this Procedure, the requirements outlined in the QMS, the customer requirements, and the specified product requirements.

Specified Product Requirements – the requirements listed within the applicable Program Procedure or as stated by the company.

Appendix B – Documentation Requirements

1. Clause 1.2.2 - Quality Manual

2. Documented Procedures:
   1) Clause 3 – training of personnel
   2) Clause 4.2 – receiving of product from outside sources
   3) Clause 4.3 – identification and traceability
   4) Clause 5.3 – control of non-conforming product

3. Records:
   1) Clause 3 – training, education, skills and/or experience
   2) Clause 4.2 – results of supplier evaluations and any necessary actions
   3) Clause 4.2 – evidence of conformity to the receiving process and it's effective operation
   4) Clause 4.3 – product identification and changes of identities
   5) Clause 4.5 – results of calibration and verification
   6) Clause 5.2.1 – customer perception
   7) Clause 5.2.4 – evidence of conformity to specified product requirements
   8) Clause 5.3 – non-conforming product and subsequent actions taken
   9) Clause 5.4.2 – corrective actions
   10) Clause 5.4.3 – preventative actions

4. Any other documents necessary to ensure the effective operation and control of the QMS.